DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service Food and Drug Administration

APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW, DISPLAY.

Form Approved: OMB No. 0910-0025 Expiration Date: October 31, 2000 See Page 4 for OMB Statement.

NOTE: No laser light abow, projection system, or device may vary from compliance with 21 CFR 1040.1 (Ic) in design or use without the approval of this application in secondance with 21 CFR 1040.1. 1. Check all applicable backs and type or print the requested information. 2. Check all applicable backs and type or print the requested information. 3. White projection to the Doctets Management Branch DFA-305), Food and Drug Administration, Rosm 1:21, 12420 Partisawn Drive, Rockville, MD 20952. 4. Enter dockst number if statement. 1. NAME OF COMPANY 1. TARKED COMMANY 1. TARKED COMMANY 1. ADDITION OF COMPANY 1. TARKED COMMANY 1. ADDITION OF COMPANY 2. ADDITION OF COMPANY 3. NAME AND TITLE OF REPONSIBILE PERSON 3. NAME AND TITLE OF REPONSIBILE PERSON 4. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are code 15. DATE OF SUBMISSION 1. TELEPHONE NO. Records are	-]	OR DEVICE	DOCKET NUMBER		
this application in accordance with 21 CRR 1010.4. INSTRUCTIONS INSTRU		1		Making as use without the program of		
1. Check all applicable boses and type of print the requested information. 2. Submit an original and four (4) copiet. 3. Mank For Company Microbian Company Control (4) Copiet. 3. ADDRESS OF COMPANY Microbia 2P Code/III P. O. Box is used, include actual street address nino. 3. NAME AND TILE OF REPONSIBLE PERSON 3. NAME AND TILE OF REPONSIBLE PERSON 4. TELEPHIONE NO. Microbial areas code/ 5. DATE OF SUBMISSION 4. TELEPHIONE NO. Microbial areas code/ 5. DATE OF SUBMISSION 7. THE APPLICANT REQUESTS THE VARIANCE TO BE IN EFFECT FOR A PERSON OF THE APPLICANT OF USED. 8. THE APPLICANT REQUESTS THE VARIANCE TO SUBMISSION THE LASER COUTT IS MOVED TO BE USED AT ANY ONE LOCATION 9. THE APPLICANT OF A SUBMISSION THE LASER COUTT SHOWING JAND PROJECTIONIS) 9. PRODUCT TOR WHICH A VARIANCE IS REQUESTED 10. ADDRESS OF SUBMISSION THE LASER COUTT SHOWING JAND PROJECTIONIS 10. ADDRESS OF SUBMISSION THE LASER COUTT SHOWING JAND PROJECTIONIS 10. ADDRESS ARE HIGHT SHOW PRODUCERS 10. ADDRESS OF SUBMISSION THE LASER COUTT SHOWING JAND PROJECTIONIS 10. ADDRESS OF SUBMISSION THE LASER COUTT SHOWING JAND PROJECTIONIS 10. ADDRESS OF SUBMISSION THE LASER COUTT SHOWING JAND PROJECTIONIS 10. ADDRESS OF SUBMISSION THE LASER COUTT SHOWING JAND PROJECTIONIS 10. ADDRESS OF SUBMISSION THE LASER COUTT SHOWING JAND PROJECTIONIS 10. ADDRESS ARE HIGHT SHOW PRODUCERS 10. ADDRESS OF SUBMISSION THE LASER COUTT SHOWING JAND PROJECTIONIS 10. PROJECTION SHOW PRODUCED FOR SALE, LEASE, OR LOAN TO OTHER LASER GIPTS THE PROJECTION TO THE STREET OF TORM FOR THE PROJECTION TO THE STREET COUTT SHOW PRODUCED TO THE STREET COUTT SHOW PRODUCE	this application in accordance with 21 CFR 1010.4.					
Requested information. Suphmit in original and four (4) copies. 1. NAME OF COMPANY 2. ADDRESS OF COMPANY (include 2TP Govellill P.O. Box is used, include actual sever address also.) 1. O Secret 86 ft. S. # \$4. New 50 K. W. W. J.	1. Cheek all analizable haves and two as ariot the	INSTRUC	CTIONS	ets Management Branch (HFA-305). Food and		
2. Submit an original and four (4) copies. 1. NAME OF COMPANY (INCOMPANY) 2. ADDRESS OF COMPANY (Include 2/2 Code/III P.O. Box is used, include actual surest address also.) 2. ADDRESS OF COMPANY (Include 2/2 Code/III P.O. Box is used, include actual surest address also.) 3. NAME AND THE GR RESPONSIBLE FERSON 2. ADDRESS OF COMPANY (Include 2/2 Code/III P.O. Box is used, include actual surest address also.) 3. NAME AND THE GR RESPONSIBLE FERSON 2. ADDRESS OF LASS FROM THE DATE OF RSUR, the great the Applicant of the Submission of P.O. ADDRESS OF THE VARIANCE TO BE IN EFFECT FOR A PERIOD OF VELSO FROM THE DATE OF RSUR, the great the Applicant many address of the submission was the estrached as part of the explication.) 7. PRODUCT DESCRIPTION AND USE 8. USIN NAME ANDIOR MODEL NUMBERS) FOR THE LASER QUIST SWONG AND PROJECTORIS! P.O. 2 C C C C S C S C S C S C S C S C S C S		J. Ma Do	ni your application to the bocke ug Administration, Room 1-23,	12420 Parklawn Drive, Rockville, MD 20852.		
T. F. COMPANY INCLUDED TO OBE USED THE PRISON 3. NAME AND THILE OF RESPONSIBLE PERSON 3. NAME AND THILE OF RESPONSIBLE PERSON 3. NAME AND THILE OF RESPONSIBLE PERSON 3. TELEPHONE NO Minched area code 4. TELEPHONE NO Minched area code 5. DATE OF SUBMISSION 10 / 12/4 G 6. THE APPLICANT REQUESTS THE VARIANCE TO BE IN EFFECT FOR A PERIOD OF YEARS FROM THE DATE OF ISSUE, the general, the appropriate processor, a particular must be attached as part of the application.] 7. PRODUCT DESCRIPTION AND USE 8. UST NAME AND/OR MODEL NUMBERIS FOR THE LASER LIGHT SHOWE) AND PROJECTORIS! 9. PROJECT OF WHICH A VARIANCE IS REQUESTED 10. A laser display device 10. A laser display device 10. A laser display device 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT ORS ARE INTENDED FOR USE IN A 10. PROJECT OR						
2. ADDRESS OF COMPANY (Include 2)P Codulit P.O. But is used, include accusul sweet address also: O	1. NAME OF COMPANY TEST COMO STAGES	1. NAME OF COMPANY				
Color Section State Section State Section State State Section State State State Section State St	2. ADDRESS OF COMPANY (Include ZIP Code)(If P.C	. Box is used, include	actual street address also.)			
Territory Reduests the Variance for any two years. If a honger period is requested, a particular to a particular variance for any two years. If a honger period is requested, a particular variance for any two years. If a honger period is requested, a particular variance as part of the application.] 7. PRODUCT DESCRIPTION AND USE b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED c. A laser display device d. A laser display device d. A projector for a laser light show d. A laser flips show d. A laser flips show and the standard is Requested. d. PRODUCT IS REPORT OF ALE, LEASE, OR LOAN TO OTHER LASER UGHT SHOW PRODUCERS d. PRODUCT FORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER UGHT SHOW PRODUCERS d. PRODUCT IS INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER UGHT SHOW PRODUCERS d. PRODUCT IS INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER UGHT SHOW PRODUCERS d. PRODUCT IS INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER UGHT SHOW PRODUCERS d. Product is show or convention d. Pranetarium or other dome projection structure d. Finester d. Pavilion d. Pranetarium or other dome projection structure d. Finester d. Policions the show or convention d. Pranetarium or other dome projection structure d. Pravilion d	103 Sect 86th St	# SA Now	Jack, NY	10028		
Territory Reduests the Variance for any two years. If a honger period is requested, a particular to a particular variance for any two years. If a honger period is requested, a particular variance for any two years. If a honger period is requested, a particular variance as part of the application.] 7. PRODUCT DESCRIPTION AND USE b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED c. A laser display device d. A laser display device d. A projector for a laser light show d. A laser flips show d. A laser flips show and the standard is Requested. d. PRODUCT IS REPORT OF ALE, LEASE, OR LOAN TO OTHER LASER UGHT SHOW PRODUCERS d. PRODUCT FORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER UGHT SHOW PRODUCERS d. PRODUCT IS INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER UGHT SHOW PRODUCERS d. PRODUCT IS INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER UGHT SHOW PRODUCERS d. PRODUCT IS INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER UGHT SHOW PRODUCERS d. Product is show or convention d. Pranetarium or other dome projection structure d. Finester d. Pavilion d. Pranetarium or other dome projection structure d. Finester d. Policions the show or convention d. Pranetarium or other dome projection structure d. Pravilion d	3. NAME AND TITLE OF RESPONSIBLE PERSON	' 4	. TELEPHONE NO. Ilnclude at	rea codel 5. DATE OF SUBMISSION		
6. THE APPLICANT REQUESTS THE VARIANCE TO BE IN EFFECT FOR A PERIOD OF	Teleron R. Cons - L	So	212 722 91	164 10/12/99		
## Sproved to prove a variance for only two years. If a longer period is requested, a justification must be attached as part of the application.] PRODUCT FOR DESCRIPTION AND USE	6 THE APPLICANT REQUESTS THE VARIANCE TO B	SE IN EFFECT FOR A P	ERIOD OF 2	YEARS FROM THE DATE OF ISSUE. (In		
8. UST NAME AND/OR MODEL NUMBERIS! FOR THE UASER LUCHT SHOWIS! Projector - Lossingtoph DSP b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED A laser display device PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER LUCHT SHOW PRODUCERS PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER ULCHT SHOW PRODUCERS PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER ULCHT SHOW PRODUCERS PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER ULCHT SHOW PRODUCERS PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER ULCHT SHOW PRODUCERS PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER UNTIL SHOW PRODUCERS PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER UNTIL SHOW PRODUCERS PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER INTENDED TO RUN FOR Less than 6 days Less than 6 months Less than 6 days Less than 6 months Less than 6 days Les	general, the Agency will approve a variance for only t	wo years. If a longer pe	riod is requested, a justification	must be attached as part of the application.)		
Projects - Loss-Taph DSP Alser display device A projector for a baser light show A laser display device A projector for a baser light show A laser display device A projector for a baser light show A laser display device A projector for a baser light show A laser display device A projector for a baser light show A laser display device A projector for a baser light show A projector device A projector A projector	7.			1		
PRODUCT FOR WHICH A VARIANCE IS REQUESTED A laser display device A projector for a laser light show PA laser fight show				,		
A laser display device A projector for a laser light show B laser fight show B laser fight show B laser fight show Cother (Specify)	Projector - Lase	rach Di	SP			
A projector for a laser light show A laser light show Completed for a laser light show or convention Completed for a laser light show or convention Completed for a laser light show	b. PRODUCT FOR WHICH A VARIANCE IS REQUEST	PRODUCT FOR WHICH A VARIANCE IS REQUESTED				
Less than 5 days Other (Specify) College	A laser display device	A laser display device				
Other (Specify) Other (Specify) OTHER LASER LIGHT SHOW PRODUCERS Description of the Composition of the Co	A projector for a laser light show					
c. PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER UCHT SHOW PRODUCERS d. PRODUCT IS INTENDED FOR USE IN A Pflanetarium or other dome projection structure Theater Hotel/motel balkroom or meeting room Store displays Tigade show or convention Discortheque or night blub Pavilion Unidoor arena Outdoor arena Outdoor arena Outdoor unenclosed area Other (Specify) At only one (fixed) location At a variety of (Tour) locations Other (Specify) At SER MEDIUM (Ar, He-Ne, etc.) At C., K.C., HQ-NQ, Nd-7qg At A Nd-7qg At A Nd-7qg At A Nd-7qg At A Nd-NQ Nd-7qg Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would liming the output power to the extent that the desired effects would not be sufficiently visible	A laser light show		·			
OTHER LASER UGHT SHOW PRODUCERS d. PRODUCT IS INTENDED FOR USE IN A Planetarium or other dome projection structure	Other (Specify)		1 ~			
d. PRODUCT IS INTENDED FOR USE IN A Planetarium or other dome projection structure Theater Theater	c. PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO		= *****			
Prianetarium or other dome projection structure	OTHER LASER LIGHT SHOW PRODUCERS					
Other (Specify)	d. PRODUCT IS INTENDED FOR USE IN A					
Photel/motel ballroom or meeting room Store displays Front screen projections Front screen pro		ure				
Store displays Tyade show or convention Sicotheque or night club Pavillion Indoor arena Outdoor arena Outdoor unenclosed area Outhor (Specify) PRODUCT IS INTENDED TO BE USED At only one (Fixed) location At a variety of (Four) locations Other (Specify) LASER MEDIUM (Ar, He-Ne, etc.) WAVE LENGTHS (Am) PEAK POWER (Watts) At , Kr , Ho -No , No - 799 PEAK POWER (Watts) 10. REASON FOR REQUESTING VARIANCE Congpliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible						
Trade show or convention Paear screen projections Paear screen project projections Paear screen	_		· · · · · · · · · · · · · · · · · · ·			
Placetheque or night club Placetheque or night club or	Y Store displays					
Pavilion Multiple reflection/diffraction effects Audience scanning (Also includes scanning any accessible uncontrolled areas Museum Reflections from stationary mirrors or mirrored surfaces (Beam Matrices) Stationary irradiation of rotating mirror balls, etc. Scanning irradiation of rotating mirror balls	☐ Trade show or convention					
Audience scanning (Also includes scanning any accessible uncontrolled areas) Outdoor arena	Discotheque or night club		1			
Museum Reflections from stationary mirrors or mirrored surfaces Reflections Stationary irradiation of rotating mirror balls, etc.						
Museum Reflections from stationary mirrors or mirrored surfaces (Beam Matrices)						
Surfaces (Beam Matrices) Other (Specify) e. PRODUCT IS INTENDED TO BE USED At only one (Fixed) location Wat a variety of (Tour) locations Other (Specify) 8. LASER MEDIUM (Ar, He-Ne, etc.) WAVE LENGTHS (Inm) PEAK POWER (watts) A1, K1, H2-N2, Nd-793 Entire Uis M2 Specifical Specifical Matrices) 9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE 10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible			<u> </u>			
Other (Specify) e. PRODUCT IS INTENDED TO BE USED At only one iffixed) location That a variety of (Tour) locations Other (Specify) 8. LASER MEDIUM (Ar, He-Ne, etc.) WAVE LENGTHS (nm) PEAK POWER (watts) A(), K(), HQ-NQ, Nd-7qq entire Us. MQ Spectrum 9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE 10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible			☑ Reflections from stationary mirrors or mirrored			
e. PRODUCT IS INTENDED TO BE USED At only one ifixed) location At a variety of (Tour) locations Other (Specify) 8. LASER MEDIUM (Ar, He-Ne, etc.) WAVE LENGTHS (nm) PEAK POWER (watts) At, Kr, He-Ne, Nd-7qg entire using the pulse duration and rate and scanning frequency and amplitude NO qud ion ce SCANNO 10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible	Outdoor unenclosed area					
At only one Fixed location Fiber optic projections Fog., smoke, or other scattering enhancement effects Other Specify Other Other Specify Other Other Other Other	Other (Specify)					
Other (Specify) Other (Specify) 8. LASER RADIATION LEVELS LASER MEDIUM (Ar, He-Ne, etc.) WAVE LENGTHS (nm) PEAK POWER (wetts) Ar, Kr, He-Ne, Nd-7qg entire uis, He spectrum 30 wets maximum 9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE NO qudion ce SCANN SCANNED Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible 100			Scanning irradiation of rotating mirror balls, etc.			
Other (Specify) 8. LASER MEDIUM (Ar, He-Ne, etc.) WAVE LENGTHS (nm) PEAK POWER (watts) Ar, Kr, He-Ne, Nd-7qg entire vis. He spectrum 30 wells maximum 9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE NO qudience SCANN 10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible	At only one (Fixed) location		Fiber optic projections			
EASER MEDIUM (Ar, He-Ne, etc.) WAVE LENGTHS (nm) PEAK POWER (watts) Ar, Kr, He-Ne, Nd-7qg entire vis. He spectrum 30 wells maximum 9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE NO qudience Scanne 10. REASON FOR REQUESTING VARIANCE Browpliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible	At a variety of (Tour) locations		Fog, smoke, or other scattering enhancement effects			
LASER MEDIUM (Ar, He-Ne, etc.) WAVE LENGTHS (nm) PEAK POWER (Watts) Ar, Kr, He-Ne, Nd-7qg entire vis. He spectrum 30 wells maximum 9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE NO qudience SCANN 10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible	Other (Specify)		Other (Specify)			
Ar, Kr, He-Ne, Nd-793 entire vis. He spectrum 30 wells maximum 9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE NO 9ndion CR SCANN 10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible	8.	LASER RADIA	TION LEVELS			
9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE 10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible	LASER MEDIUM (Ar, He-Ne, etc.)	WAVE LEN	IGTHS (nm)	PEAK POWER (watts)		
10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible	Ar, Kr, He-Ne, Nd-799	entire vis.	He spectrum	30 wetts maxmum		
10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible		;				
10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible						
10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible				AND AND THE		
10. REASON FOR REQUESTING VARIANCE Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible	1			CANNING PREQUENCY AND AMPLITUDE		
Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible	no quoi on ce scanning					
Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible	10. REASON FOR REQUESTING VARIANCE					
limit the output power to the extent that the desired effects would not be sufficiently visible	P Compliance with the limits of 21 CFR 1040	0.11(c) would restrict	the intended use of the produ	uct because compliance would		
The state of the s	limit the output power to the extent that the	e desired effects wou	aid not be sufficiently visible			

r 1	. MANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICABLE STANDARD
	It is proposed to deviate from the provisions of 21 CFR 1040.11(c) in that the accessible emission level would exceed the accessible emission limits specified in 21 CFR 1040.11(c).
	☐ It is proposed to deviate from the provisions of 21 CFR 1040.11(c) as follows:
12	ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION
	Laser light shows and displays are accepted popular media in entertainment and the arts. Use of power levels in excess of the limits imposed by 21 CFR 1040.11(c) is necessary to achieve the required effects in these media.
	Other or additional advantages (describe and explain).
13	EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. (Check as many boxes as apply, in item 14 "Remarks,"
	justify any boxes not checked, using additional sheets as necessary. State any other means of radiation protection that will be used.)
	a. D All laser products, systems, shows, and projectors will be certified to comply with 21 CFR 1040.10 and the conditions of this variance and will be reported as required by 21 CFR 1002.10 AND 1002.11 using the reporting guides provided for such purpose. These actions will be accomplished prior to any introduction into commerce.
	b. Effects not specifically indicated in this variance application will not be performed. No other effects will be added until an amendment to the variance has been obtained and the required reports or supplements, as applicable, have been submitted.
	c. Scanning, projection, or reflection of laser and collateral radiation (Light show radiation) into audience or other accessible uncontrolled areas will not be permitted except for diffuse reflections produced by the atmosphere, added atmospheric scattering media, and target screens.
	d. Laser radiation levels in excess of the limits of Class I will not be permitted at any point less than 3.0 meters above any surface upon which persons other than operators, performers, or employees are permitted to stand or 2.5 meters below or in lateral separation from any place where such persons are permitted to be. Operators, performers, and employees will not be required or allowed to view radiation above the limits of Class I or be exposed to radiation above the limits specified in 21 CFR 1040.11(c).
	e. Many product which relies on scanning to meet access, exposure, or product class limits will incorporate a scanning safeguard system which directly senses scanner motion and which will react fast enough to preclude exceeding the applicable limit.
	f. MAll laser light shows shall be under the direct and personal control of trained, competent operator(s). The operator(s) will:
	(1) Be an employee of the variance holder who will be responsible for the training and the conduct of the operator;
	(2) Be located where all beam paths can be directly observed at all times; and
	(3) Immediately terminate the emission of light show radiation in the event of any unsafe condition; or, for outdoor shows, upon request by any air traffic control officials.
	g. The maximum laser projector output power will not exceed the level required to obtain the intended effects.
	h. If The projection system (i.e., the projector and all other components used to produce the lighting effects) will be securely mounted or immobilized to prevent unintended movement or misalignment. Beam masking will be provided as an inherent part of the system design to prevent overfilling of screens, beam stops, targets, etc.
	i. Laser projectors will not be delivered to any other party under an agreement of sale, lease, or loan unless and until the recipient demonstrates that they have a variance in effect at the time of delivery that permits them to produce laser light shows incorporating such projector(s).
	j. In addition to the requirements of 21 CFR 1040.10(h), the manufacturer of laser projectors/systems will provide to parties who purchase, lease, or borrow the equipment, adequate users' instructions for safe installation and operation which explain the responsibility of the recipient as an independent light show manufacturer to submit the required reports and apply for and obtain a variance from CDRH prior to introduction into commerce of any laser light shows.
	k. The requirements of 21 CFR 1002.30(a)(1) and (2) will be accomplished through the use of written procedures for setup, alignment, testing, and performance of each show, these procedures will be in sufficient detail to ensure compliance with 21 CFR 1040.10, the conditions of this variance, and the control of access to radiation areas using the procedures described in the ANSIZ136.1 standard for the safe use of lasers (American National Standards Institute, 1430 Broadway, New York, NY 10018) or any other equivalent user consensus standard and, where applicable, state or local requirements. Laser radiation areas which can contain radiation levels above the limits specified in 21 CFR 1040.11(c) will be clearly identified by the posting of warning signs and/or restricting access through physical means (such as pressure switches, photo cells, barriers, guards, etc.). These requirements apply to temporary areas (such as during set up and alignment procedures) and to final or permanent areas. The variance holder will retain the records of these procedures and the results of all tests as required by 21 CFR 1002.31. A copy of the variance application, the approval letter, current procedures, and records relating to each particular show will be with the operator or other responsible individual and will be made available for inspection by FDA and other responsible authorities.

- 1. Advance written notification will be made as early as possible to appropriate federal, state, and local authorities providing show itinerary with dates and locations clearly and completely identified, and a basic description of the proposed effects including a statement of the maximum power output intended. Such notifications will be made, but not necessarily be limited, to:
 - (1) The Center for Devices and Radiological Health, Office of Compliance (HFZ-342), 2098 Gaither Road, Rockville, MD 20850, providing the initial and closing dates for fixed installations and the itinerary for mobile shows. In addition, unless all aspects of each show have been reported and accession numbers clearly referenced, each notice will include detailed descriptions of each show and a listing of all effects to be performed in sufficient detail to confirm compliance with the regulations and this variance.
 - (2) The Federal Aviation Administration (FAA) for any projections into open airspace at any time (i.e., including set up, alignment, rehearsals, performances, etc.). If the FAA objects to any laser effects, the objections will be resolved and any conditions requested by FAA will be adhered to. If these conditions cannot be met, the objectionable effects will be deleted from the show
 - (3) State and local radiation control offices/agencies for all shows to be performed within their jurisdictions. All requirements of state and local law will be satisfied and any objections raised by local authorities will be resolved or the effects deleted. (A list of federal and state offices is available from the Center for Devices and Radiological Health upon request.)

14. REMARKS

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete, and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading or incorrect in any material way. I have submitted and will submit all reports required by 21 CFR 1002.10 and 1002.11 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health, to supply such other information as may be necessary to evaluate and act on this application.

15. SIGNATURE

16. NAME (Type or Print)

Star L. Cone

17. TITLE

sole proprieter